

### **III. REMARKS**

#### **Status of the Claims**

Claims 1-7 and 10-53 remain in the case. The previous allowance of Claims 1-7, 10-15, 18-28, and 42-44 has been withdrawn by the Examiner.

#### **Claim Rejections Under 35 U.S.C. § 103**

Claims 1, 2, 16, 29, 31-34, 37-44, and 45-53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bergamini. Independent claims 33, 45, 48, and 51 were previously amended such that these claims are directed to non-topical administration as suggested by the Examiner. All independent claims are, therefore, directed to non-topical administration.

The Office Action alleges that recitations in the pending claims are statements of intended use and do not impart any further physical or material limitation and cites MPEP 2111.02, "Preamble Statements Reciting Purpose or Intended Use."

First, Applicant notes that none of the recitations relating to non-topical administration appear in the preamble of any pending claims. Furthermore, the limitation of non-topical administration is not merely a statement of intended use as alleged, but a material limitation well known to one of skill in the art.

One of skill in the art would understand that the route of administration of any pharmaceutical affects absorption rate, efficacy, composition of the pharmaceutical carrier, and preparation. REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 710-12, 1495-97, 1524-26 (19th ed. 1995)(attached hereto). Specifically, parenteral routes "by definition include any route other than oral-gastrointestinal (enteral) tract, but in common medical usage the term excludes topical administration." *Id.* at 710-11.

A major consideration affecting formulation of solutions, emulsions, suspensions, or extracts includes whether the drug is for external (topical), internal (non-topical), or ophthalmic

use. *Id.* at 1495-96. That choice then affects other considerations including drug concentration, physical and chemical stability of the drug, preservation of the preparation, and use of appropriate excipients. *Id.* at 1495. Further, parenteral dosage forms “differ from all other drug dosage forms because of the unique requirements imposed because they are injected directly into body tissue” and “must be exceptionally pure and free from physical, chemical, and biological contaminants.” *Id.* at 1524. Thus, one of skill in the art would readily recognize that choosing a non-topical route of administration will materially affect the composition of the final formulation.

Applicant’s recitations that the currently claimed formulations are for non-topical administration provides a material limitation and not merely a recitation of intended use. One of skill in the art will recognize that a composition designed for non-topical administration requires a different formulation that would not likely be appropriate for a topical formulation. Further, Bergamini fails to provide any teaching or suggestion to use any of the formulations allegedly described for any route of administration other than ocular or otic. Bergamini neither teaches or suggests that his compositions could be used for non-topical administration as described in the present invention.

As the Applicant has provided a material limitation readily recognized by one of skill in the art, the rejection is improper and respectfully requests that the rejection be withdrawn.

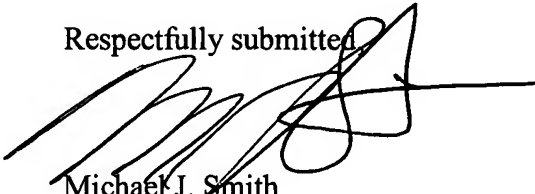
### **Claim Objections**

The Examiner objects to claims 3-15, 17-28, 30, 35, and 36 as depending from a rejected base claim. Applicant submits that based on the remarks herein, the Examiner’s objections are overcome and requests that the objections be withdrawn.

### **Conclusion**

Applicant submits that, based on the Remarks herein, the claims are in condition for allowance and such favorable action is respectfully requested. If the Examiner has any questions or comments that might accelerate allowance of these claims, he is invited to contact the undersigned representative at (512) 542-8530.

Respectfully submitted,



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